



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2018-D-3759]**

### **Considerations for the Development of Dried Plasma Products Intended for Transfusion; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Considerations for the Development of Dried Plasma Products Intended for Transfusion; Guidance for Industry.” The guidance document provides recommendations intended to assist manufacturers, sponsors, and applicants developing dried plasma products intended for transfusion in order to facilitate the availability of safe and effective dried plasma products in the United States. The guidance document provides considerations for the successful development and licensing of dried plasma products and for the approval of devices used to manufacture dried plasma. The guidance includes recommendations on optimal sources of input plasma; manufacturing and product quality, including product characterization; packaging and reconstitution; clinical studies; and device submissions. The guidance announced in this notice finalizes the draft guidance of the same title dated October 2018.

**DATES:** The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2018-D-3759 for “Considerations for the Development of Dried Plasma Products Intended for Transfusion; Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015,

or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jenifer Stach, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a document entitled “Considerations for the Development of Dried Plasma Products Intended for Transfusion; Guidance for Industry.” This guidance provides recommendations intended to assist manufacturers, sponsors, and applicants

developing dried plasma products intended for transfusion in order to facilitate the availability of safe and effective dried plasma products in the United States. This guidance provides considerations for the successful development and licensing of dried plasma products and for the approval of devices used to manufacture dried plasma. The guidance includes recommendations on optimal sources of input plasma; manufacturing and product quality, including product characterization; packaging and reconstitution; clinical studies; and device submissions.

Plasma is a critical component of early transfusion therapy in the management of traumatic hemorrhage. Plasma can replenish various coagulation proteins that are consumed during the coagulopathy that may accompany traumatic injury. Because plasma products intended for transfusion such as fresh frozen plasma, plasma frozen within 24 hours after phlebotomy, and plasma frozen within 24 hours after phlebotomy held at room temperature up to 24 hours after phlebotomy are stored frozen, these products need to be thawed prior to transfusion. This limits or prevents the use of plasma in settings where freezers and other support equipment are unavailable (e.g., battlefields, remote locations, and other austere settings), and may lead to delayed administration. Dried plasma (such as freeze-dried or spray-dried plasma) offers the potential to address these challenges by providing a product that is stable at ambient temperatures, and which can be rapidly reconstituted and transfused.

In the *Federal Register* of October 30, 2018 (83 FR 54597), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated October 2018.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on considerations for the

development of dried plasma products intended for transfusion. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 211 have been approved under OMB control number 0910-0139; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338; the collections of information in 21 CFR part 610 have been approved under OMB control numbers 0910-0116, 0910-0139, and 0910-0338; the collections of information in 21 CFR part 630 have been approved under OMB control number 0910-0116; the collections of information in 21 CFR part 640 have been approved under OMB control number 0910-0116; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics> or <https://www.regulations.gov>.

Dated: December 16, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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